



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I-NEW ENGLAND
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

URGENT MATTER - PROMPT REPLY NECESSARY
CERTIFIED MAIL - RETURN RECEIPT REQUESTED

AUG 21 2015

Mr. Jeffrey Davis, Chief Operations Officer
Sheffield Pharmaceuticals
170 Broad Street
New London, CT 06320

Re: **NOTICE OF VIOLATION** of the applicable Generators Standards of Hazardous *Waste*, *Section 3002 of the Resource Conservation and Recovery Act of 1976 (RCRA)* and the Hazardous and Solid Waste Amendments (HSWA) of 1984, 42 U.S.C. §§ 6622(a) and 6924(d) through (m) and the Regulations of Connecticut State Agencies (RCSA):22a-449(c)-102 and 22a-449(c)-108.

Dear Mr. Davis:

On December 2, 2014, representatives of the United States Environmental Protection Agency ("EPA") conducted a RCRA Compliance Evaluation Inspection. The purpose of this inspection was to determine the compliance of Sheffield Pharmaceuticals, EPA ID No. CTD001155217, with Connecticut Hazardous Waste Regulations RCSA 22a-449(c)-102 and 22a-449(c)-108 and the federal Hazardous Waste Management Regulations found at 40 CFR Parts 260-272. The State of Connecticut has been granted final authorization by EPA to administer certain portions of RCRA.

As a result of the inspection noted above, EPA has determined that your facility violated certain provisions of the Connecticut Hazardous Waste Regulations and the RCRA regulations, promulgated at 40 CFR Parts 260 through 272. The specific violations are set forth below:

1. **Failure to maintain closed hazardous waste containers during storage, except when it is necessary to add or remove waste, as required by RCSA 22a-449(c)-102(a)(1), which incorporates by reference 40 CFR 262.34(a)(1) and 40 CFR 265.173(a).**

Specifically, the following hazardous waste containers were not closed at the time of the inspection, as required by RCSA 22a-449(c)-102(a)(1), which incorporates by reference 40 CFR 262.34(a)(1) and 40 CFR 265.173(a):

Quality Control Chemistry Lab

The following three, open, Satellite Accumulations Area (SAA) containers, attached to a UPLC and HPLC, that had covers, but the cap hole was too large for the tubing attached to both the HPLC and UPLC:

2 4-liter brown glass containers, in secondary containment, labeled, Hazardous waste, methanol, acetonitrile and phosphate buffer
1- 16-gallon poly container, labeled, Hazardous waste, flammable liquid, toxic, nos chloroform, ethyl ether.

By email dated 12/12/14, the facility documented that the facility replaced the caps with a tighter fit.

2. **Failure to properly determine if a waste is a hazardous waste, as required by RCSA 22a-449(c)- 102(a)(1), which incorporates by reference 40 CFR 262.11 and 40 CFR 262.40(c).**

Specifically, at the time of the inspection, the facility failed to properly determine if the waste was hazardous for the following containers, in accordance with RCSA 22a-449(c)-102(a)(1), which incorporates by reference 40 CFR 262.11 and 40 CFR 262.40(c):

In the Rejected Materials Area, the inspection team observed five boxes containing small containers of expired material that was from the Chemistry Lab and R&D Lab. Jeffrey Davis stated that the high value extracts will be sold to a surplus chemical buyer.

By email dated 12/22/14, the facility sent a table that designated if the expired material contained in these 5 boxes was hazardous waste, the corresponding waste code and the weight of the material or if it was non-hazardous. The following material was designated as hazardous waste, labeled accordingly and put in the HWSA:

Chemical name	Weight (pounds)
Parsley seed oil, D001	1.7
Flavor #22, D001	1.7
Calcium peroxide FG, D001, D002	1.3
Flavor #481 Thursday Plantatio, D001	0.1
Ammonium molybdate TS, D002	0.1
Dibutyl phthalate, U069	0.9
Dehydrated alcohol, D001	0.4

And in May 2014, 6,400 pounds of non-hazardous liquid, waste zinc oxide rinse water, CR04 was manifested off site as non-hazardous, on manifest

0127270070JJJ, dated May 12, 2014. At the destination facility, where it was sampled with the result of pH=13, the manifest was changed to: corrosive liquid, basic, inorganic, potassium hydroxide, D002. At the time of the inspection, Jeffrey Davis thought that detergent might have gotten into this load.

3. **Failure to label or mark each container accumulating hazardous waste on-site with the words "Hazardous Waste" and other words that identify the contents such as chemical name, as required by RCSA 22a-449(c)-102(a)(2)(J) and 22a-449(c)-102(a)(2)(E).**

Specifically, at the time of the inspection, the following containers were not labeled or marked with the words, "Hazardous Waste" and other words that identify contents such as chemical name, as required by RCSA 22a-449(c)-102(a)(2)(J) and 22a-449(c)-102(a)(2)(E):

1 55-gallon container, marked, n-butyl alcohol, located in the Flammable Room.
1 5-gallon container, marked, corrosive, Linphos 85FG-K, balance water, 85% phosphoric acid-food grade, rejected 7/18/14, located in the Rejected Materials Area.

According to an email dated 12/10/2014, the facility stated that these two containers were moved to the HWSA on 12/03/2014.

4. **Failure to label or clearly mark each lamp or container in which such lamps are contained with any of the following phrases "Universal Waste- Lamp(s)", "Waste Lamp(s)", or "Used Lamp(s)", as required by RCSA 22a-449(c)-113(a)(1), which incorporates by reference 40 CFR 273.14(e).**

Specifically, the following universal waste containers were not labeled with any of the following phrases "Universal Waste- Lamp(s)", "Waste Lamp(s)", or "Used Lamp(s)", as required by RCSA 22a-449(c)-113(a)(1), which incorporates by reference 40 CFR 273.14(e):

One 5-ft. cardboard container, labeled, bad lamps, 11/6/2014
Three 2-ft. cardboard container, labeled, no good, 11/11/14
Two 5-ft. cardboard container, labeled, bad lamps, 9/29/2014
One 4-ft. cardboard container, labeled, bad lamps, 9/30/14

You are hereby required to:

1. Immediately upon receipt of this NOTICE:
 - a. Keep hazardous waste containers closed during storage, except when it is necessary to add or remove waste, as required by RCSA 22a-449(c)-102(a)(1), which incorporates by reference 40 CFR 262.34(a)(1) and 40 CFR 265.173(a).

- b. Determine if a waste is a hazardous waste, as required by RCRA 22a-449(c)-102(a)(1), which incorporates by reference 40 CFR 262.11 and 40 CFR 262.40(c).
- c. Label or mark each container accumulating hazardous waste on-site with the words "Hazardous Waste" and other words that identify the contents such as chemical name, as required by RCRA 22a-449(c)-102(a)(2)(J) and 22a-449(c)-102(a)(2)(E).
- d. Label or clearly mark each lamp or container in which such lamps are contained with any of the following phrases "Universal Waste- Lamp(s)", "Waste Lamp(s)", or "Used Lamp(s)", as required by RCRA 22a-449(c)-113(a)(1), which incorporates by reference 40 CFR 273.14(e).

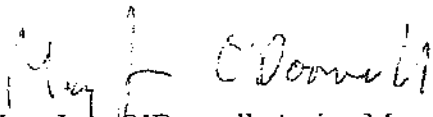
2. Within (30) thirty calendar days of receipt of this **NOTICE**:

- a. Submit a written description, with supporting documentation, of the actions taken to correct the aforementioned violations to:

Linda Brolin, Environmental Engineer
U.S. Environmental Protection Agency
5 Post Office Square, Suite 1100
Mail Code: OES05-4
Boston, MA 02109

Failure to correct the violation as required by this **NOTICE** may subject the facility to further federal enforcement action, including the assessment of penalties, pursuant to Section 3008 of RCRA 42, U.S.C. § 6928.

If you have any questions regarding this **NOTICE**, please contact Linda Brolin, at (617) 918-1876. Sincerely,


Mary Jane O'Donnell, Acting Manager
RCRA, EPCRA, and Federal Programs Unit

cc: Joseph Schiavone, CT DEEP